UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,968	06/30/2006	Aaron Kaplan	ANVIL.001BNP1	9697

20995 7590 11/23/2009

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
DORNBUSCH, DIANNE	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
11/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,968	KAPLAN ET AL.	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-24,37-44,47 and 49-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-24,37-44,47 and 49-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/6/09, 9/11/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 14-18, 23, 43, 44, and 52-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Von Oepen (2002/0151959).

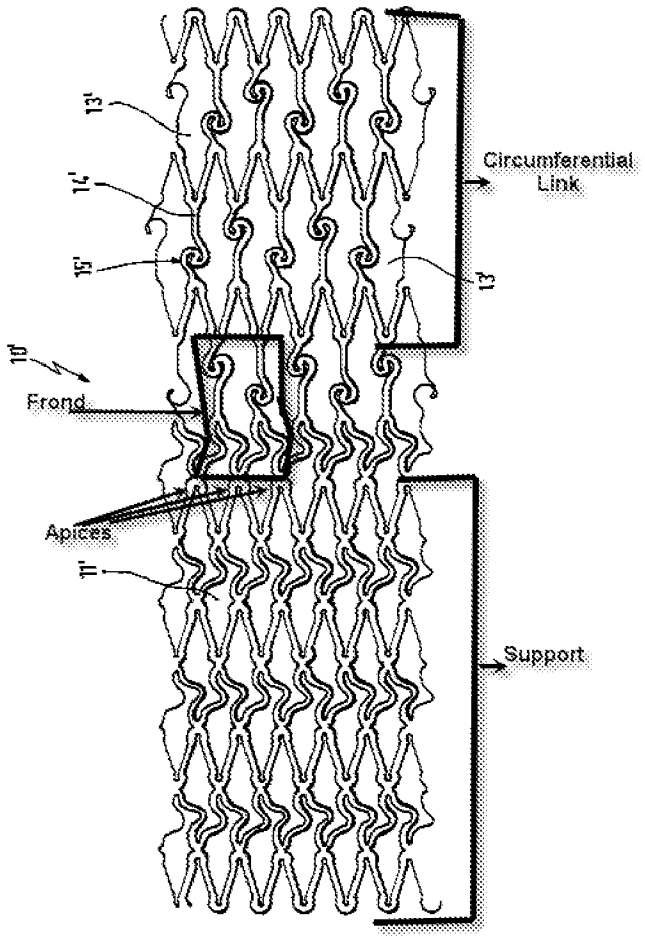
Von Oepen discloses the following claimed limitations:

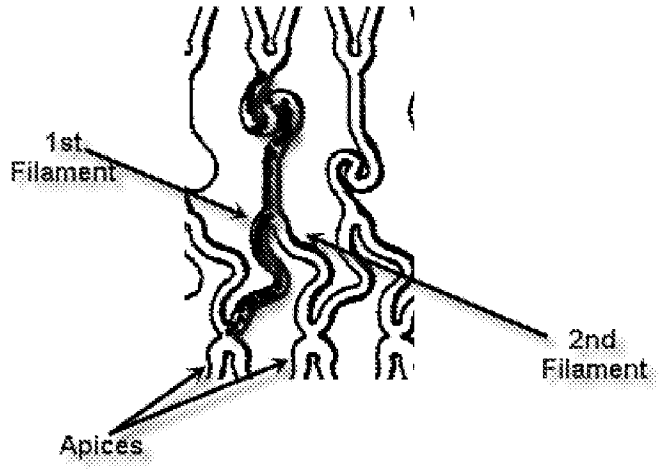
Claim 14: A prosthesis for placement at an opening from a main body lumen to a branch body lumen, the prosthesis comprising: a radially expansible support (see figure below), the support configured to be deployed in at least a portion of the branch body lumen, the support adapted to provide a first radial force to support a body lumen; at least two elongate, flexible fronds (see figure below where one frond is enclosed) extending from an end of the support, each frond having a first end, a second end, and an axially elongate portion having a plurality of crests and troughs between the first and second ends (see figure below), the axially elongate portion comprising first and second spaced apart filaments (see figure below where the first filament is shaded) each having first and second ends (see figure below), the first end of the first filament being directly connected to a first proximal apex of the radially expansible support (see figure below), the first end of the second filament being directly connected to a second proximal apex of the radially expansible support the first proximal apex being spaced apart from the

second proximal apex the second end of the second filament being coupled with the first filament at a location between the first and second ends of the frond (see figure below), the fronds extending from an end of the support and configured to be positioned across the opening and into the main body lumen; at least one circumferential link connected to the second ends of the fronds (see figure below), the circumferential link spaced axially apart from the support by the fronds and adapted to provide a second radial force that is less than the first radial force (see figure below); and a plurality of elongate side wall openings in between adjacent fronds sized and configured to receive a stent deployment device therethrough; the elongate, flexible fronds, the support and the circumferential link defining a unitary body as deployed, the elongate side wall openings in between adjacent fronds for facilitating crossing of a main vessel stent therethrough when the support is positioned in the branch body lumen and the circumferential link is positioned in the main body lumen (see figure below).

Regarding the statements with respect to the side wall openings function, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

With respect to the adapted to statements, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.


13'
14'
15'
Circumferential Link
13'
10'
Frond
Apices
11'
Support


1st Filament
2nd Filament
Apices

Claim 15: Wherein the circumferential link comprises an undulating pattern having at least three apexes (see figure above).

Claim 16: Comprising three fronds (see figure above).

Claim 17: Wherein at least one frond comprises a helical configuration (see figure above).

Claim 18: Comprising a plurality of helical fronds (see figure above).

Claim 23: The prosthesis comprising an endothelial cell ingrowth surface (Fig. 2). The surface is capable of promoting cell ingrowth.

Claim 43: That the circumferential link comprises a single transverse filament (see figure above).

Claim 44: Comprising a transition section between the support and the fronds (see figure above).

Claim 52: Wherein the second end of the second filament is coupled with a side portion of the first filament (see figure above).

Claim 53: A prosthesis for placement at an opening from a main body lumen to a branch body lumen, the prosthesis comprising: a radially expansible support (see figure above), the support configured to be deployed in at least a portion of the branch body lumen; at least two elongate, flexible fronds (see figure above where one frond is enclosed) extending from an end of the support, each frond having a first end, a second end, and an elongate portion extending axially between the first and second ends (see figure above); and a circumferential link connected to the second ends of the fronds (see figure above), the circumferential link spaced axially apart from the support by the

fronds (see figure above); wherein the first end of each of the fronds is directly connected to a plurality of spaced apart apices of the radially expansible support (see figure above); and wherein the second end of each of the fronds is directly connected to the circumferential link at a single location (see figure above).

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim 54: Wherein first end of the fronds is connected to three spaced apart apices of the radially expansible support (see figure above).

Claim 55: Wherein the radially expansible support is adapted to provide a first radial force to support the branch body lumen and the circumferential link is adapted to provide a second radial force that is less than the first radial force when applied to the main body lumen.

With respect to the adapted to statements, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim 56: Wherein fronds further comprises first and second spaced apart filaments having distal and proximal ends, the distal ends of each of the first: and second filaments being directly coupled with spaced apart proximal apices of the radially expanded support (see figure above).

Claim 57: Where the proximal end of the second filament is coupled with a side portion of the first filament between the distal and proximal ends of the first filament (see figure above).

Claim 58: A plurality of elongate side wall openings in between adjacent fronds sized and configured to receive a stent deployment balloon catheter therethrough (see figure above).

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Von Oepen (2002/0151959) in view of Summers et al. (5,342,387).

Von Oepen teaches all the claimed limitations discussed above however, Von Oepen does not disclose a lubricous coating.

Summer discloses that at least a portion of the at least one frond comprises a lubricous coating (Col. 4 Lines 27-30). The surface of the stent (this includes the fronds) is coated with a gel coating which causes the surface to be smooth (Col. 4 Lines 36-40).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Von Oepen with a lubricous coating in view of the teachings of Summer, in order to have a smooth surface to avoid abrasions on the vessel wall.

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Von Oepen (2002/0151959).

Von Oepen discloses the claimed invention except for the axial length of the fronds being at least 8mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the length of the fronds at least 8mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

6. Claims 21, 22, 37-41, 47, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Oepen (2002/0151959) in view of Callol et al. (2002/0183763).

Claims 21 and 22:

Von Oepen discloses all the claimed limitations discussed except for the circumferential link being radiopaque.

Callol discloses a prosthesis with a radially expansible support (26), the support configured to be deployed in at least a portion of the branch body lumen ([0140] last sentence); at least two elongate, flexible frond (39 where each frond is each portion that extends from the support 26 to the peak) each having a first end (the portion connected to the support (26)), a second end (the end of the peaks which connects to portion (29)), and a length between; and at least one circumferential link (proximal portion of 29) connected to the second end of the fronds (39).

Additionally Callol discloses the following claimed invention:

Claim 21: That the circumferential link is radiopaque ([0148] first sentence). The link is made from a ring (30) and strut (31) which can have variable thicknesses that provide higher radiopacity therefore they are radiopaque.

Claim 22: That the circumferential link has a greater radiopacity than the frond. The radiopacity of the link as disclosed in paragraph [0152] varies depending on the thickness of the ring (30) and the strut (31) therefore the link is capable of having higher radiopacity than the frond. Furthermore, the frond (39) is not radiopaque which indicates that the link will have higher radiopacity than the frond.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Von Oepen with the circumferential link being radiopaque in view of the teachings of Callol, in order to be able to see the link as it is being delivered to the desired vessel position.

Claims 37-41, 47, and 49:

Von Oepen discloses all the claimed limitations discussed except for a drug coating.

Callol discloses the following claimed limitations:

Claim 37: That at least a portion of the radially expansible support (26) comprises a drug coating ([0150] Lines 1-2), and at least a portion of the fronds (39) and the circumferential link (29) are without a drug coating (Claim 20). It is disclosed that the device can be coated completely or only portions which indicates that the fronds and link are not coated.

Claim 38: That the drug coating is configured to produce a controlled drug release rate ([0150] Lines 9-11).

Claim 39: That the drug is one of an anti-cell prolifertive ([0150] Lines 18-19), anti cell migration, anti-neo plastic, anti inflammatory drug ([0150]).

Claim 40: That the drug is configured to reduce restensosis ([0150] Lines 1-4).

Claim 41: That the drug coating includes a first coating and a second coating ([0150] Lines 4-11).

Claims 47 and 49: That the drug is incorporated into a polymer matrix wherein the polymer includes a base layer and a top layer (a first and second coating), the drug being incorporated into at least one of the top layer and the base layer ([0150] Lines 4-11).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Von Oepen with a drug coating in view of the

teachings of Callol, in order to assist in repair of the vessel and may be useful, for example, in reducing the likelihood of the development of restenosis ([0152]).

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Von Oepen (2002/0151959) in view of Jayaraman (5,755,781).

Von Oepen teaches all the claimed limitations discussed however, Von Oepen does not disclose a non thrombogenic surface.

Jayaraman discloses a prosthesis (Fig. 4 and 7) with a support (the part 11 located at the distal portion) and a circumferential link (part 11 at the proximal portion) with fronds (71) connecting the link and support together (Fig. 4 and 7). The prosthesis comprising a non thrombogenic surface (Col. 6 Lines 35-37)

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Von Oepen with a non thrombogenic surface in view of the teachings of Jayaraman, in order to prevent the adherence of blood clots to the surface of the prosthesis.

8. Claims 42, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Oepen (2002/0151959) in view of Callol et al. (2002/0183763) and further in view of Jang (2004/0106985).

Claim 42:

Von Oepen in view of Callol teaches all the claimed limitations discussed above however, Von Oepen in view of Callol does not disclose that the first coating is configured to produce a first drug release rate and the second coating is configured to produce a second drug release rate.

Jang discloses that the first coating is configured to produce a first drug release rate and the second coating is configured to produce a second drug release rate ([0351]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Von Oepen in view of Callol with different release rates for the drug coatings in view of the teachings of Jang, in order to control the amount of drug that is released as well as to better enable safe encapsulation of the implanted stent.

Claims 50 and 51:

Von Oepen in view of Callol teaches all the claimed limitations discussed above however, Von Oepen in view of Callol does not disclose that the prosthesis includes one or more reservoirs configured to be loaded with one or more drugs.

Jang discloses that the prosthesis includes one or more reservoirs (27) configured to be loaded with one or more drugs ([0352] first sentence).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Von Oepen in view of Callol with reservoirs for loading one or more drugs in view of the teachings of Jang, in order to facilitate the retention and delivery of the drugs.

Response to Arguments

9. Applicant's arguments filed July 6, 2009 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773